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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/880,711	06/12/2001	Alejandro Abuin	LEX-0191-USA	5531

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EXAMINER

CROUCH, DEBORAH

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 05/19/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/880,711

Applicant(s)

ABUIN ET AL.

Examiner

Deborah Crouch, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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Applicant's election without traverse of group IV, claim 8, in Paper No. 10 is acknowledged. The amendment received March 25, 2003 has been entered.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 8 is rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial, and credible asserted utility or a well established utility.

The specification does not set forth a specific, substantial, and credible asserted utility for a murine embryonic stem cell line comprising an engineered mutagenic sequence in a gene comprising an exon sequence disclosed in SEQ ID NO: 328. The specification does not disclose any gene that comprises the exon, nor does the specification describe the structure of the gene. There is no identification of an open reading frame, coding region, start codons, or stop codons with regards to SEQ ID NO: 328. Further the specification does not disclose a function of the encoded protein. Since the function of the gene is unknown and uncharacterized, cell cannot be used for any of the disclosed utilities. The specification states the isolation of SEQ ID NO: 328 from embryonic stem cells suggest an involvement in developmental and cell differentiation processes (page 7, lines 26-28). The specification also states that "knockout" animals can be made using the ES cells (specification, page 80, lines 12-15). However, in neither cite is the function of the gene having SEQ ID NO: 328 or its encoded protein disclosed as acting at a particular of development or differentiation, nor is there any disclosure as to the particular use of the knockout animal. The specification clearly indicates that the function of SEQ ID NO: 328 is not known, and discloses that the ES cells comprising the gene having an exon of SEQ ID NO: 328 will be useful in determining the function of the gene (specification, page 6, lines 20-24). As the function of

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the gene having SEQ ID NO: 328 and is encoded protein is not known, the invention of claim 8 provides no immediate benefit to those of skill in the art. To have a benefit, and therefore utility, more experimentation is required to characterize and identify its function in development. Further, the specification does not disclose a function for the gene having mutagenic sequence engineered into the gene having an exon of SEQ ID NO: 328. There is no disclosure as to which, if any, cellular function would be altered because of the mutagenic sequence. Therefore, the isolated murine embryonic stem cell line cannot be considered a research tool but rather is a material to be experimented upon to determine its use. For patentability, the claimed invention has to be in a useful form currently with specific benefit. The courts have stated in *Brenner V Manson* 148 USPQ 689,

"[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field" (at 695) and "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion" at 696.

Thus claim 8 fails to have utility because it lacks specific benefit in a currently available form and the requirement on the artisan to experiment on the invention of claim 8 renders any patent issuing with claim 8 the equivalent of a "hunting license." Therefore, claim 8 lacks patentability under 35 U.S.C. 101.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The legal support for this written description is found in an analysis of relevant case law. *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

SEQ ID NO: 328 contains wild-cards ("n") or unknown nucleotides at several nucleotide positions. As such, these sequences are not considered to be described because the complete structure, that is nucleotide sequence, of SEQ ID NO: 328 cannot be envisioned. Further SEQ ID NO: 328 consists of 400 nucleotides in length. To one of skill in the art, these sequences are not of sufficient length that one would believe that they reflect a complete gene and no complete genes containing these sequences are described (for example, by structure, function, or location). As such, the claimed subject matter cannot be deemed adequately described by the specification such that skilled artisan would realize that applicant had possession of the mouse embryonic stem cell of claim 8. Therefore

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conception would not be achieved until reduction to practice has occurred outside of the specification. Adequate written description requires more than a mere statement that it is part of the invention. The nucleic acid sequence of the breadth of the claims required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Thus, without the complete structure of SEQ ID NO: 328, and the gene that contains it, applicant has not provided evidence that they were in possession of the invention at the time of filing.

Claim 8 is rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial, and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 is unclear in the phrase "an exon sequence disclosed in SEQ ID NO: 328." SEQ ID NO: 328 contains only one exon sequence. The phrase reads as though it contains more than one exon sequence.

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The claims are free of the prior art. At the time of filing, the art did not teach or suggest SEQ ID NO: 328, or a mouse embryonic stem cell line comprising an engineered mutagenic sequence in a gene comprising an exon sequence disclosed in SEQ ID NO: 328.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is 703-308-1126. The examiner can normally be reached on M-Th, 8:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J. Reynolds can be reached on 703-305-4051. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Deborah Crouch, Ph.D.
Primary Examiner
Art Unit 1632

dc
May 16, 2003